




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460


OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 7/7/2020

Subject: Efficacy Review for CWN-07-W, EPA Reg. No. 46781-RT
(DP Barcode: 455892, E-Submission: 44867)

From: Samantha Collins
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P) 

Thru: Thao Pham, Team Lead
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P) 
Date Signed: June 26, 2020

To: Joseph Varco, Acting PM 33 / Jake McFarley
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: METREX RESEARCH.
1717 West Collins Avenue
Orange, CA 92867

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Isopropyl Alcohol	17.20%
Didecyl dimethyl ammonium chloride	0.17%
Alkyl (C14-50%, C12-40%, C16-10%) dimethyl benzyl ammonium chloride.....	0.11%
Other Ingredients.....	<u>82.52%</u>
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): RTU towelette

Submission type: New product

Currently registered efficacy claim(s): Hard, non-porous surface RTU towelette disinfectant (bactericidal, virucidal, tuberculocidal, fungicidal), and non-food contact sanitizer.

Requested action(s): Review of new data

Documents considered in this review:

- Letter from applicant to EPA dated November 26, 2019
- Data Matrix (EPA Form 8570-35) dated November 22, 2019
- 41 new efficacy studies (MRIDs 50964711 - 50964752); 50964733 is superseded by 51199301.
- Efficacy review, dated 6/4/20 for MRID 50964735.
- Proposed label dated November 2019
- Confidential Statement of Formula (EPA Form 8670-4).

II PROPOSED DIRECTIONS FOR USE

“To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces:

To disinfect hard, non-porous surface to be surfaces. Use [enough] [Product Name] wipes to treat the surface [to remain visibly wet] for 2 minutes [2-minute [contact time] [dwell time]]. [Rinse.] [Let air dry]. Gross filth and heavy soil loads must be removed prior to disinfecting. [If streaking is observed, wipe with a clean, damp [cloth or] paper towel after 2-minute contact time [dwell time] has expired.] [Use 2-minute contact time [dwell time] for (Tuberculosis) [-or-] (TB).]”

III STUDY SUMMARIES

1.	MRID	50964711	Study Completion Date:	8/20/2019		
Study Objective		Disinfection, Bactericidal				
Testing Lab; Lab Study ID		Accuratus, A28199				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> (ATCC 6538)				
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection				
Application Method		Towelettes				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	19-2197RDO-W, 19-5198RDO-W, 19-6198RDO-W				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% FBS				
Carrier type, # per lot		Glass slides, 60 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH 48%
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80				
Reviewer comments (i.e. protocol deviations etc.)		N/A				

2.	MRID	50964712	Study Completion Date:	8/28/2019		
Study Objective		Disinfection, Bactericidal				
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, A28216				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442)				
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection				
Application Method		Towelettes				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	19-2197RDO-W, 19-5198RDO-W, 19-6198RDO-W				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% FBS				
Carrier type, # per lot		Glass slides, 60 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH 44%
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80				
Reviewer comments (i.e. protocol deviations etc.)		N/A				

3.	MRID	50964713	Study Completion Date:		8/28/2019		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, A28217					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Salmonella enterica</i> (ATCC 10708)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	19-2197RDO-W, 19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 60 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH	47%
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations etc.)		N/A					

4.	MRID	50964714	Study Completion Date:		9/26/2019		
			Amended Report Date:		11/21/2019		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-941					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Enterococcus faecium</i> (ATCC 51559)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	55%
Neutralizer		BHI Broth + 1% Lecithin + 7% Polysorbate					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <p>The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.</p>					

	<p>Protocol Deviation: The Confirmation of challenge microorganism section of the protocol states that the streaks will be incubated for 24±2 hours. The exact time the streaks were removed from incubation was not documented; therefore, it cannot be confirmed that the incubation requirement was achieved. Since there was sufficient growth on the streaks to confirm the identity of the challenge microorganism this deviation had no negative impact.</p> <p>Note: Per ATCC, the challenge microorganism is classified as Multi Drug-Resistant; antibiotic resistance confirmation demonstrates resistance against Gentamicin and Vancomycin.</p>
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5.	MRID	50964715	Study Completion Date:	9/25/2019			
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-942					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Klebsiella pneumoniae</i> (ATCC 4352)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <p>The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.</p>					

6.	MRID	50964716	Study Completion Date:		9/25/2019		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-943					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Acinetobacter baumannii</i> (ATCC 19606)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		Protocol amendments: 1. The protocol identifies the challenge microorganism as ATCC strain BAA-1605. This is a typographical error; the correct strain identification is ATCC 19606. 2. The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.					

7.	MRID	50964717	Study Completion Date:		9/25/2019	
Study Objective		Disinfection, Bactericidal				
Testing Lab; Lab Study ID		Microbac, 198-952				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O157:H7 (ATCC 35150)				
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection				
Application Method		Towelettes				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W				
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A				
Soil load		5% FBS				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH 60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80				
Reviewer comments (i.e. protocol deviations etc.)		Protocol amendments: The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.				

8.	MRID	50964718	Study Completion Date:		9/10/2019	
Study Objective		Disinfection, Bactericidal				
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, A28390				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Legionella pneumophila</i> (ATCC 33153)				
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection				
Application Method		Towelettes				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W				
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A				
Soil load		5% FBS				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH 56%
Neutralizer		Lethen Broth + 0.14% Lecithin + 1% Tween 80				
Reviewer comments (i.e. protocol deviations etc.)		N/A				

9.	MRID	50964719	Study Completion Date:		9/25/2019		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-953					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Micrococcus luteus</i> (ATCC 14408)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		Protocol amendments: The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.					

10.	MRID	50964720	Study Completion Date:		9/25/2019		
			Amended Report Date:		11/21/19		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-954					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Burkholderia cepacia</i> (ATCC 25416)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		Protocol amendments: The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of					

	Letheen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Letheen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.
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11.	MRID	50964721	Study Completion Date:		9/26/2019		
			Amended Report Date:		11/21/19		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-956					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Streptococcus mutans</i> (ATCC 25175)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	55%
Neutralizer		BHI Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments: The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Letheen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Letheen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.</p> <p>Protocol Deviation: The Confirmation of challenge microorganism section of the protocol states that the streaks will be incubated for 24±2 hours. The exact time the streaks were removed from incubation was not documented; therefore, it cannot be confirmed that the incubation requirement was achieved. Since there was sufficient growth on the streaks to confirm the identity of the challenge microorganism this deviation had no negative impact.</p>					

12.	MRID	50964722	Study Completion Date:		9/23/2019	
Study Objective		Disinfection, Bactericidal				
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, A28389				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Bordetella pertussis</i> (ATCC 12743)				
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection				
Application Method		Towelettes				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W				
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A				
Soil load		5% FBS				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	19°C	RH 55%
Neutralizer		Lethen Broth + 0.14% Lecithin + 1% Tween 80				
Reviewer comments (i.e. protocol deviations etc.)		N/A				

13.	MRID	50964723	Study Completion Date:		9/10/2019	
Study Objective		Disinfection, Bactericidal				
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, A28391				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Moraxella catarrhalis</i> (ATCC 25240)				
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection				
Application Method		Towelettes				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W				
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A				
Soil load		5% FBS				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH 50%
Neutralizer		Lethen Broth + 0.14% Lecithin + 1% Tween 80				
Reviewer comments (i.e. protocol deviations etc.)		N/A				

14.	MRID	50964724	Study Completion Date:		9/25/2019	
Study Objective		Disinfection, Bactericidal				
Testing Lab; Lab Study ID		Microbac, 198-958				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Stenotrophomonas maltophilia</i> (ATCC 25596)				
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection				
Application Method		Towelettes				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W				
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A				
Soil load		5%				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH 60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80				
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <ol style="list-style-type: none"> 1. The carrier preparation and inoculation section of the protocol states that the inoculated carriers will be dried at 25-30°C. This is a typographical error; the inoculated carriers will be dried 36±1°C. 2. The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds. 				

15.	MRID	50964725	Study Completion Date:		9/26/2019	
Study Objective		Disinfection, Bactericidal				
Testing Lab; Lab Study ID		Microbac, 198-959				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Streptococcus pyogenes</i> (ATCC 12344)				
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection				
Application Method		Towelettes				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W				
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A				
Soil load		5% FBS				
Carrier type, # per lot		Glass slides, 10 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH 55%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80 + 5% Defibrinated Sheep's Blood				
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <ol style="list-style-type: none"> 1. The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds. 2. Due to the opacity of the neutralizer, following incubation, all test and control tubes will be streaked on TSA+ and incubated for 24±2 hours at 36±1°C. All results for growth or no growth will be based on the results of the streaks. <p>Protocol Deviation: The Confirmation of challenge microorganism section of the protocol states that the streaks will be incubated for 24±2 hours. The exact time the streaks were removed from incubation was not documented; therefore, it cannot be confirmed that the incubation requirement was achieved. Since there was sufficient growth on the streaks to confirm the identity of the challenge microorganism this deviation had no negative impact.</p>				

16.	MRID	50964726	Study Completion Date:				9/26/2019	
			Amended Report Date:				11/21/19	
Study Objective		Disinfection, Bactericidal						
Testing Lab; Lab Study ID		Microbac, 198-960						
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Penicillin-Resistant <i>Streptococcus pneumoniae</i> (ATCC 700677)						
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection						
Application Method		Towelettes						
Test Substance Preparation	Name/ID	CWN-07-W						
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W						
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A						
Soil load		5% FBS						
Carrier type, # per lot		Glass slides, 10 per batch						
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	55%	
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80 + 5% Defibrinated Sheep's Blood						
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <ol style="list-style-type: none"> 1. The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds. 2. Due to the opacity of the neutralizer, following incubation, all test and control tubes will be streaked on TSA+ and incubated for 24±2 hours at 36±1°C. All results for growth or no growth will be based on the results of the streaks. <p>Protocol Deviation: The Confirmation of challenge microorganism section of the protocol states that the streaks will be incubated for 24±2 hours. The exact time the streaks were removed from incubation was not documented; therefore, it cannot be confirmed that the incubation requirement was achieved. Since there was sufficient growth on the streaks to confirm the identity of the challenge microorganism this deviation had no negative impact.</p> <p>Antibiotic resistance confirmation demonstrates that organism is resistant to penicillin.</p>						

17.	MRID	50964727	Study Completion Date:	9/25/2019			
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-961					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Vancomycin-Resistant <i>Enterococcus faecalis</i> (ATCC 51575)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <p>The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.</p> <p>Antibiotic resistance confirmation demonstrates resistance against Vancomycin.</p>					

18.	MRID	50964728	Study Completion Date:	9/25/2019			
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-962					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Methicillin-Resistant <i>Staphylococcus aureus</i> (ATCC 33592)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <p>The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.</p> <p>Antibiotic resistance confirmation demonstrates resistance against Oxacillin.</p>					

19.	MRID	50964729	Study Completion Date:		9/25/2019		
			Amended Report Date:		11/21/19		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-963					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Carbapemen-Resistant <i>Klebsiella pneumoniae</i> (ATCC BAA-1705)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Letheen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		Protocol amendments: The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Letheen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Letheen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.					

20.	MRID	50964730	Study Completion Date:	9/26/2019			
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-964					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Multi Drug-Resistant <i>Acinetobacter baumannii</i> (ATCC BAA-1605)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <ol style="list-style-type: none"> 1. The protocol identifies the challenge microorganism as ATCC strain 19606. This is a typographical error; the correct strain identification is ATCC BAA-1605. 2. The Verification of antibiotic resistance section of the protocol indicates that the appropriate antibiotic disc is Vancomycin. This is a typographical error; the appropriate antibiotic discs are Ceftazidime and Gentamicin as identified in the media and reagents section of the protocol. 3. Lot number 2 identified in the Miscellaneous Information Section of the protocol is incorrect; the correct lot number is 19-4225RDO-W. 4. The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds. <p>Antibiotic resistance confirmation demonstrates that the organism is resistant to Ceftazidime and Gentamicin.</p>					

21.	MRID	50964731	Study Completion Date:		9/26/2019		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-965					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Vancomycin-Intermediate <i>Staphylococcus aureus</i> (ATCC 700699)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	60-61%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments: The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.</p> <p>Antibiotic resistance confirmation demonstrates intermediate resistance to Vancomycin.</p>					

22.	MRID	50964732	Study Completion Date:		10/17/2019		
			Amended Report Date:		11/21/19		
Study Objective		Disinfection, Bactericidal					
Testing Lab; Lab Study ID		Microbac, 198-944					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		NDM-1-Positive <i>Enterobacter cloacae</i> (CDC AR-0038)					
Test Method		Pre-Saturated Towelettes for Hard Surface Disinfection					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2224RDO-W, 19-4225RDO-W					
	Preparation	Tested concentration: Nominal Dilution: RTU Diluent: N/A					
Soil load		5%					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	64-65%
Neutralizer		Lethen Broth + 1% Lecithin + 7% Polysorbate 80					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments:</p> <ol style="list-style-type: none"> 1. The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of letheen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml letheen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds. 2. The protocol identifies the challenge microorganism as NDM-1-Positive <i>Enterobacter cloacae</i>, CDC 100654. Per the CDC, the correct identification of the challenge microorganism is NDM-1-Positive <i>Enterobacter cloacae</i>, CDC AR- 0038. 3. There is a typographical error in the antibiotic disc identified in the Verification of antibiotic resistance section of the protocol. The correct antibiotic disc is imipenem. 4. On Project Sheet No. 2, Deviation No. 1 indicates that the geometric average of the carrier counts was 6.3 x 1 as CFU/carrier. At the request of the sponsor, the calculations were clarified by adjusting to show an additional significant figure since the average CFU/carrier is calculated using the full value. With the additional significant figure the average CFU/carrier is now 6.49 x 1 as CFU/carrier (rounded to 6.5 x 1 as CFU/carrier). <p>Antibiotic resistance confirmation demonstrates resistance against Imipenem.</p>					

23.	MRID	50964734	Study Completion Date:		9/26/2019		
Study Objective		Disinfection, Fungicidal					
Testing Lab; Lab Study ID		Microbac, 198-945					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Candida albicans</i> , ATCC 10231					
Test Method		Testing Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection Additional Organism <i>C. albicans</i>					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	55%
Neutralizer		Lethen Broth containing 7% Polysorbate 80 + 1% Lecithin					
Reviewer comments (i.e. protocol deviations etc.)		<p>Protocol amendments: The Carrier Counts procedures in the protocol state that dried carriers will be placed into individual tubes containing 10 ml of Lethen Broth and subjected to ultrasound for 1 minute±5 seconds in a cleaning sonicator. The correct procedures are as follows: dried carriers will be placed into individual tubes containing 20 ml Lethen Broth and the tubes will be vortex-mixed for 120 seconds±5 seconds.</p> <p>Protocol Deviation: The Confirmation of challenge microorganism section of the protocol states that the streaks will be incubated for 24±2 hours. The exact time the streaks were removed from incubation was not documented; therefore, it cannot be confirmed that the incubation requirement was achieved. Since there was sufficient growth on the streaks to confirm the identity of the challenge microorganism this deviation had no negative impact.</p>					

24.	MRID	50964735	Study Completion Date:	10/15/2019			
Study Objective		Disinfection, Fungicidal					
Testing Lab; Lab Study ID		Microbac, 198-946					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Candida auris</i> , (CDC AR Bank#0381)					
Test Method		OECD Quantitative Method for Evaluating the Efficacy of Liquid Antimicrobials against <i>C. auris</i>					
Application Method		Towelettes					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2256RDO-W, 19-4256RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
	Preparation	Ready to Use- the canister was inverted three times to ensure the wipes were saturated. Following, 5 wipes were pulled from the center of the roll and discarded. Using subsequent towelettes (2) the test substance was aseptically expressed into the sterile container and covered until use.					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	22°C	RH	40-46%
Neutralizer		Dey Engley (D/E) Broth					
Reviewer comments (i.e. protocol deviations etc.)		<p>There is a two-minute contact time on the label, but it was tested at 1 minute 52 seconds.</p> <p>The laboratory reports a log CFU/carrier recovered as as 0.00 and negative log value (indicating a substitution for 0 CFU). For clarification, it is requested the laboratory provide the raw numbers (CFU) for recovery from each of the carriers as well as the calculations/substitutions leading to a negative log reduction value.</p>					

24.	MRID	50964735	Study Completion Date:		10/15/2019		
Experimental Start Date		9/20/2019					
Study Objective		Wetness Determination for Towelette Products					
Testing Lab; Lab Study ID		Microbac; 198-946					
Test Method		Wetness Determination (per EPA web guidance)					
Test Substance Preparation	Name/ID	CWN-07-W EPA Reg. No. 46781-RT					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2256RDO-W 19-4256RDO-W					
	Preparation	towelettes					
Carrier type, # per lot		150x20 mm glass Petri dish, 3					
Test conditions		Contact time	1 minute 52 seconds	Temp	21°C	RH	40%
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		<p>Supporting gravimetric and visual wetness reported at 1 minute 52 seconds for all 3 test carriers per batch.</p> <p>For the wetness determination the testing lab should use the actual contact time rather than an abbreviated one because they are looking for residual wetness for the contact time on the label.</p> <p>Based on the data and their pictures, for this product an additional 8 seconds would likely not have mattered.</p>					

25.	MRID	50964736	Study Completion Date:		8/21/2019		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Accuratus, A28204					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Herpes simplex virus type 1 (ATCC VR-733, Strain F1)					
Indicator Cell Culture		Vero cells (ATCC CCL-81)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	-
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations etc.)							

26.	MRID	50964737	Study Completion Date:	8/27/2019			
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Accuratus, A28181					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Herpes simplex virus type 2 (ATCC VR-734, Strain FG)					
Indicator Cell Culture		Vero cells (ATCC CCL-81)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	22°C	RH	-
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations etc.)							

27.	MRID	50964738	Study Completion Date:	8/28/2019			
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Accuratus, A28177					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Influenza A virus, ATCC VR-544, Strain A/Hong Kong/8/68					
Indicator Cell Culture		MDCK (canine Kidney) cells (ATCC CCL-34)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	-
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations etc.)							

28.	MRID	50964739	Study Completion Date:		8/27/2019		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Accuratus, A28178					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72					
Indicator Cell Culture		MDCK (canine Kidney) cells (ATCC CCL-34)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	22°C	RH	-
Neutralizer		Sephadex Gel Filtration Columns					
Reviewer comments (i.e. protocol deviations etc.)							

29.	MRID	50964740	Study Completion Date:		10/17/2019		
		Amended Report Date:		11/22/19			
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Microbac, 198-947					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Human orthopneumovirus (Respiratory Syncytial Virus), Strain: Long, ATCC VR-26					
Indicator Cell Culture		HeLa cells, ATCC CCL-2					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% serum (unspecified)					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH	52-54%
Neutralizer		MEM + 10% NCS + 0.5% Polysorbate 80 + 0.5% Lecithin					
Reviewer comments (i.e. protocol deviations etc.)							

30.	MRID	50964741	Study Completion Date:		10/24/2019	
Study Objective		Disinfection, Virucidal				
Testing Lab; Lab Study ID		Microbac, 198-949				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		SARS-associated Coronavirus, Strain: CDC 200300592, ZeptoMetrix/CDC				
Indicator Cell Culture		Vero E6 cells, source: ATCC CRL-1586				
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces				
Application Method		Towelette				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-2256RDO-W, 19-4256RDO-W				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5% serum (unspecified)				
Carrier type, # per lot		Glass petri dish, 1 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH 47-49%
Neutralizer		MEM + 10% FBS + 0.5% Polysorbate 80 + 0.5% Lecithin				
Reviewer comments (i.e. protocol deviations etc.)						

31.	MRID	50964742	Study Completion Date:		10/24/2019	
		Amended Report Date:		1/14/20		
Study Objective		Disinfection, Virucidal				
Testing Lab; Lab Study ID		Microbac, 198-950				
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Measles Virus, Strain: Edmonston, ATCC VR-24				
Indicator Cell Culture		Vero cells, source: ATCC CCL-81				
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces				
Application Method		Towelette				
Test Substance Preparation	Name/ID	CWN-07-W				
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W				
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A				
Soil load		5%				
Carrier type, # per lot		Glass petri dish, 1 per batch				
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH 41%
Neutralizer		MEM + 10% FBS + 0.5% Polysorbate 80 + 0.5% Lecithin				
Reviewer comments (i.e. protocol deviations etc.)						

32.	MRID	50964743	Study Completion Date:		9/24/2019		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest, A28442					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Parainfluenza virus type 3, ATCC VR-93, Strain C243					
Indicator Cell Culture		MDBK (bovine kidney) cells (ATCC CCL-22)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	22°C	RH	-
Neutralizer		Sephadex Gel Filtration Column					
Reviewer comments (i.e. protocol deviations etc.)							

33.	MRID	50964744	Study Completion Date:		9/4/19		
		Amended Report Date:		11/22/19			
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Microbac, 198-931					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Duck Hepatitis B virus Strain: Grimaud, Hepadna Virus Testing, Inc.					
Indicator Cell Culture		Primary Duck Hepatocytes, Metzger Farms					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		100% duck serum					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	55-56%
Neutralizer		MEM + 10% FBS + 0.5% Polysorbate 80 + 0.5% Lecithin					
Reviewer comments (i.e. protocol deviations etc.)							

34.	MRID	50964745	Study Completion Date:		8/23/19		
			Amended Report Date:		11/22/19		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Microbac, 198-932					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Bovine Viral Diarrhea Virus, strain: NADL, American BioResearch Lab					
Indicator Cell Culture		MDBK cells, ATCC CCL-22					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% serum (unspecified)					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH	50-51%
Neutralizer		MEM + 10% Horse Serum + 0.5% Polysorbate 80 + 0.5% Lecithin					
Reviewer comments (i.e. protocol deviations etc.)							

35.	MRID	50964746	Study Completion Date:		9/4/19		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Microbac, 198-932					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Human Immunodeficiency Virus Type 1 (HIV-1), Strain: IIIB, ZeptoMetrix					
Indicator Cell Culture		C8166 cells, University of Pennsylvania					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% serum (unspecified)					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	21°C	RH	51%
Neutralizer		RPMI 1640 + 10% FBS + 0.5% Polysorbate 80 + 0.5% Lecithin					
Reviewer comments (i.e. protocol deviations etc.)							

36.	MRID	50964747	Study Completion Date:		8/22/19		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Accuratus, A28205					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Feline Calicivirus as a surrogate virus for Norovirus					
Indicator Cell Culture		CRFK cells (ATCC CCL-94)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	22°C	RH	-
Neutralizer		Sephadex Gel Filtration Column					
Reviewer comments (i.e. protocol deviations etc.)		Batch 19-5198RDO-W did not demonstrate complete inactivation					

37.	MRID	50964748	Study Completion Date:		10/24/19		
		Amended Report Date:		11/22/19			
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Microbac, 198-951					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Enterovirus 71, Strain: H Source: ATCC VR-1432					
Indicator Cell Culture		LLC-MK2 cells, Source: ATCC CCL-7.1					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5%					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	20-21°C	RH	49-51%
Neutralizer		MEM + 10% NCS + 0.5% Polysorbate 80 + 0.5% Lecithin					
Reviewer comments (i.e. protocol deviations etc.)							

38.	MRID	50964749	Study Completion Date:		9/23/19		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Analytical Lab Group, A28433					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Adenovirus type 2, ATCC VR-846, Strain Adenoid 6					
Indicator Cell Culture		A-549 (human lung carcinoma) cells (ATCC CCL-185)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	22°C	RH	-
Neutralizer		Sephadex Gel Filtration Column					
Reviewer comments (i.e. protocol deviations etc.)							

39.	MRID	50964750	Study Completion Date:		9/24/19		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Analytical Lab Group, A28417					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Human Rotavirus, ATCC VR-2018, Strain WA					
Indicator Cell Culture		MA-104 (Rhesus monkey kidney) (ATCC CRL-2378.1)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH	-
Neutralizer		Sephadex Gel Filtration Column					
Reviewer comments (i.e. protocol deviations etc.)							

40.	MRID	50964751	Study Completion Date:		9/26/19		
Study Objective		Disinfection, Virucidal					
Testing Lab; Lab Study ID		Analytical Lab Group, A28443					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Echovirus type 11, ATCC VR-41, Strain Gregory					
Indicator Cell Culture		Rhesus monkey kidney (RMK cells) (Diagnostic Hybrids)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-5198RDO-W, 19-6198RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass petri dish, 1 per batch					
Test conditions		Contact time	1 min 52 sec	Temp	20°C	RH	-
Neutralizer		Sephadex Gel Filtration Column					
Reviewer comments (i.e. protocol deviations etc.)		Batches 19-5198RDO-W and 19-6198RDO-W did not demonstrate complete inactivation					

41.	MRID	51199301	Study Completion Date:		4/30/19		
Study Objective		Disinfection, Tuberculocidal					
Testing Lab; Lab Study ID		Analytical Lab Group, A29092					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Mycobacterium bovis</i> (ATCC 35743)					
Test Method		Virucidal Efficacy of a Test Substance for Use on Inanimate, Nonporous Surfaces					
Application Method		Towelette					
Test Substance Preparation	Name/ID	CWN-07-W					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	19-1288RDO-W, 19-2289RDO-W					
	Preparation	Tested concentration: LCL Dilution: RTU Diluent: N/A					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		Contact time	2 min	Temp	20°C	RH	10%
Neutralizer		Horse Serum + 0.1% Tween 80					
Reviewer comments (i.e. protocol deviations etc.)							

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID	Organism	No. Exhibiting Growth/Total No. Tested			Mean log ₁₀ Density
		Batch 19- 2197RDO-W	Batch 19- 5198RDO-W	Batch 19- 6198RDO-W	
1 minute 52 second contact time, towelette, 5% soil load					
50964711	<i>Staphylococcus aureus</i> (ATCC 6538)	1/60	1/60	1/60	5.63
50964712	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	0/60	0/60	0/60	5.57
50964713	<i>Salmonella enterica</i> (ATCC 10708)	0/60	0/60	0/60	4.97

MRID	Organism	No. Exhibiting Growth/Total No. Tested		Mean log ₁₀ Density
		Batch 19-2224RDO-W	Batch 19-4225RDO-W	
1 minute 52 second contact time, towelette, 5% soil load				
50964714	<i>Enterococcus faecium</i> (ATCC 51559)	0/10	0/10	6.32
50964715	<i>Klebsiella pneumoniae</i> (ATCC 4352)	0/10	0/10	5.5
50964716	<i>Acinetobacter baumannii</i> (ATCC 19606)	0/10	0/10	5.9
50964717	<i>Escherichia coli</i> O157:H7 (ATCC 35150)	0/10	0/10	6.2
50964718	<i>Legionella pneumophila</i> (ATCC 33153)	0/10	0/10	5.22
50964719	<i>Micrococcus luteus</i> (ATCC 14408)	0/10	0/10	6.5
50964720	<i>Burkholderia cepacia</i> (ATCC 25416)	0/10	0/10	4.47
50964721	<i>Streptococcus mutans</i> (ATCC 25175)	0/10	0/10	6.37
50964722	<i>Bordetella pertussis</i> (ATCC 12743)	0/10	0/10	4.67
50964723	<i>Moraxella catarrhalis</i> (ATCC 25240)	0/10	0/10	5.23
50964724	<i>Stenotrophomonas maltophilia</i> (ATCC 25596)	0/10	0/10	6.45
50964725	<i>Streptococcus pyogenes</i> (ATCC 12344)	0/10	0/10	6.5
50964726	Penicillin-Resistant <i>Streptococcus pneumoniae</i> (PRSP) (ATCC 700677)	0/10	0/10	4.94

50964727	Vancomycin-Resistant <i>Enterococcus faecalis</i> (VRE) (ATCC 51575)	0/10	0/10	6.3
50964728	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	0/10	0/10	6.1
50964729	Carbapenem-Resistant <i>Klebsiella pneumoniae</i> (CRKP) (ATCC BAA-1705)	0/10	0/10	6.12
50964730	Multi Drug-Resistant <i>Acinetobacter baumannii</i> (ATCC BAA-1605)	0/10	0/10	6.3
50964731	Vancomycin-Intermediate <i>Staphylococcus aureus</i> (VISA), (ATCC 700699)	0/10	0/10	6.5
50964732	New Delhi metallo-beta-lactamase 1 (NDM-1-Positive) <i>Enterobacter cloacae</i> (CDC AR-0038)	0/10	0/10	5.71

Disinfection – Fungicidal Efficacy

MRID	Organism	No. Exhibiting Growth/Total No. Tested		Mean log ₁₀ Density
		Batch 19-5198RDO-W	Batch 19-6198RDO-W	
1 minute 52 second contact time, towelette, 5% soil load				
50964734	Candida albicans, ATCC 10231	0/10	0/10	4.4

MRID	Organism	Batch No.	Results		AVG. log ₁₀ CFU/Carrier
			Average log 10 CFU/Carrier	Log Reduction	
1 minutes 52 seconds contact time, towelette, 5% fetal bovine serum					
50964735	Candida auris, AR Bank#0381	19-2256 RDO-W	-0.30	≥5.87	5.87±0.08
		19-4256 RDO-W	0.00	5.97	5.97±0.05

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)
			19-5198 RDO-W	19-6198 RDO-W	
1 minute 52 second contact time, towelette, 5% soil load					
50964736	Herpes simplex virus type 1 (ATCC VR-733, Strain F1)	10 ⁻¹ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	5.30
		Log ₁₀ TCID ₅₀ /carrier	≤0.80	≤0.80	
		Log Reduction	≥4.50	≥4.50	
50964737	Herpes simplex virus type 2 (ATCC VR-734, Strain FG)	10 ⁻¹ to 10 ⁻⁹ dilution	Complete inactivation	Complete inactivation	5.55
		Log ₁₀ TCID ₅₀ /carrier	≤0.80	≤0.80	
		Log Reduction	≥4.75	≥4.75	
50964738	Influenza A virus, Strain A/Hong Kong/8/68, ATCC VR-1679	10 ⁻¹ dilution	Cytotoxicity	Cytotoxicity	6.80
		10 ⁻² to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	
		Log ₁₀ TCID ₅₀ /carrier	≤1.80	≤1.80	
		Log Reduction	≥5.00	≥5.00	
50964739	Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72	10 ⁻¹ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	5.05
		Log ₁₀ TCID ₅₀ /carrier	≤0.80	≤0.80	
		Log Reduction	≥3.25*	≥3.25*	
50964740	Human orthopneumovirus (Respiratory Syncytial Virus), Strain: Long, ATCC VR-26	10 ⁻⁴ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	6.05
		Log ₁₀ TCID ₅₀ /carrier	≤2.80	≤2.80	
		Log Reduction	≥3.25	≥3.25	
50964741	SARS-associated Coronavirus, Strain: CDC 200300592, ZeptoMetrix/CDC	10 ⁻⁴ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	6.30
		Log ₁₀ TCID ₅₀ /carrier	≤2.80	≤2.80	
		Log Reduction	≥3.50	≥3.50	
50964742	Measles Virus, Strain: Edmonston, ATCC VR-24	10 ⁻⁴ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	6.05
		Log ₁₀ TCID ₅₀ /carrier	≤2.80	≤2.80	
		Log Reduction	≥3.25	≥3.25	
50964743	Parainfluenza virus type 3, ATCC VR-93, Strain C243	10 ⁻¹ dilution	Complete inactivation	Cytotoxicity	5.80
		10 ⁻² to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	
		Log ₁₀ TCID ₅₀ /carrier	≤0.80	≤2.05	
		Log Reduction	≥4.00*	≥3.75	

MRID	Organism	Description	Results		Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)
			19-5198 RDO-W	19-6198 RDO-W	
1 minute 52 second contact time, towelette, 5% soil load					
50964744	Duck Hepatitis B virus Strain: Grimaud, Hepadna Virus Testing, Inc.	10 ⁻³ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	4.93
		Log ₁₀ TCID ₅₀ /carrier	≤1.80	≤1.80	
		Log Reduction	≥3.13	≥3.13	
50964745	Bovine Viral Diarrhea Virus, strain: NADL, American BioResearch Lab	10 ⁻⁴ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	6.05
		Log ₁₀ TCID ₅₀ /carrier	≤2.80	≤2.80	
		Log Reduction	≥3.25	≥3.25	
50964746	Human Immunodeficiency Virus Type 1 (HIV-1), Strain: IIIB, ZeptoMetrix	10 ⁻⁴ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	7.23
		Log ₁₀ TCID ₅₀ /carrier	≤4.10	≤4.10	
		Log Reduction	≥3.13	≥3.13	
50964747	Feline Calicivirus as a surrogate virus for Norovirus	10 ⁻¹ dilution	Cytotoxicity	Cytotoxicity	4.80
			2/4	T/4	
		10 ⁻² to 10 ⁻⁴ dilution	Complete inactivation	Complete inactivation	
			Log ₁₀ TCID ₅₀ /carrier	≤1.80	
		Log Reduction	1.30	≤1.05	
			≥3.00	≥3.00	
50964748	Enterovirus 71, Strain: H Source: ATCC VR-1432	10 ⁻⁴ dilution	2/4	1/4	6.30
		10 ⁻⁵ to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	
		Log ₁₀ TCID ₅₀ /carrier	3.30	3.05	
		Log Reduction	3.00	3.25	
50964749	Adenovirus type 2, ATCC VR-846, Strain Adenoid 6	10 ⁻² to 10 ⁻⁸ dilution	Complete inactivation	Complete inactivation	5.30
		Log ₁₀ TCID ₅₀ /carrier	≤1.80	≤1.80	
		Log Reduction	≥3.50	≥3.50	
50964750	Human Rotavirus, ATCC VR-2018, Strain WA	10 ⁻¹ to 10 ⁻⁸ dilution	Complete inactivation	Complete inactivation	7.05
		Log ₁₀ TCID ₅₀ /carrier	≤0.80	≤0.80	
		Log Reduction	≥5.25*	≥5.25*	

MRID	Organism	Description	Results		Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)
			19-5198 RDO-W	19-6198 RDO-W	
1 minute 52 second contact time, towelette, 5% soil load					
50964751	Echovirus type 11, ATCC VR-41, Strain Gregory	10 ⁻¹ dilution	1/4	2/4	4.80
		10 ⁻² to 10 ⁻⁸ dilution	Complete inactivation	Complete inactivation	
		Log ₁₀ TCID ₅₀ /carrier	≤1.05	≤1.30	
		Log Reduction	≥3.00*	≥3.00*	

* Accounts for cytotoxicity in the 10⁻¹ dilution per cytotoxicity control results.

Disinfection – Tuberculocidal Efficacy, *Mycobacterium bovis* BCG (ATCC 35743)

Distribution: Tuberculosis: Etiology, Mycobacterium tuberculosis H37Rv (ATCC 35961),					
MRID	Lot	Medium			Carrier Control Count (Average CFU/Carrier)
		MPB	7H9	KM	
2 minute contact time, 5% soil load, 90 day incubation					
51199301 (4/30/20)	19-1288RDO-W	0/10	0/10	0/10	5.34
	19-2289RDO-W	0/10	0/10	0/10	

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50964711	Disinfection, Bactericidal	Hard, non-porous surfaces	Towelette	2 minutes	5%	N/A	• <i>Staphylococcus aureus</i> (ATCC 6538)	Yes
50964712							• <i>Pseudomonas aeruginosa</i> (ATCC 15442)	
50964713							• <i>Salmonella enterica</i> (ATCC 10708)	
50964714							• <i>Enterococcus faecium</i> (ATCC 51559)	
50964715							• <i>Klebsiella pneumoniae</i> (ATCC 4352)	
50964716							• <i>Acinetobacter baumannii</i> (ATCC 19606)	
50964717							• <i>Escherichia coli</i> O157:H7 (ATCC 35150)	
50964718							• <i>Legionella pneumophila</i> (ATCC 33153)	
50964719							• <i>Micrococcus luteus</i> (ATCC 14408)	
50964720							• <i>Burkholderia cepacia</i> (ATCC 25416)	

50964721							<ul style="list-style-type: none"> • <i>Streptococcus mutans</i> (ATCC 2175) 	
50964722							<ul style="list-style-type: none"> • <i>Bordetella pertussis</i> (ATCC 12743) 	
50964723							<ul style="list-style-type: none"> • <i>Moraxella catarrhalis</i> (ATCC 25240) 	
50964724							<ul style="list-style-type: none"> • <i>Stenotrophomonas maltophilia</i> (ATCC 25596) 	
50964725							<ul style="list-style-type: none"> • <i>Streptococcus pyogenes</i> (ATCC 12344) 	
50964726							<ul style="list-style-type: none"> • Penicillin-Resistant <i>Streptococcus pneumoniae</i> (PRSP) (ATCC 700677) 	
50964727							<ul style="list-style-type: none"> • Vancomycin-Resistant <i>Enterococcus faecalis</i> (VRE) (ATCC 51575) 	
50964728							<ul style="list-style-type: none"> • Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) (ATCC 33592) 	
50964729							<ul style="list-style-type: none"> • Carbapenem-Resistant <i>Klebsiella pneumoniae</i> (CRKP) (ATCC BAA-1705) 	
50964730							<ul style="list-style-type: none"> • Multi Drug-Resistant <i>Acinetobacter baumannii</i> (ATCC BAA-1605) 	
50964731							<ul style="list-style-type: none"> • Vancomycin-Intermediate <i>Staphylococcus</i> 	

50964732							<i>aureus</i> (VISA), (ATCC 700699) • New Delhi metallo-beta-lactamase 1 (NDM-1-Positive) <i>Enterobacter cloacae</i> (CDC AR-0038)	
50964733	Disinfection, Tuberculocidal	Hard, non-porous surfaces	Towelette	2 minutes 45 seconds	5%	N/A	• <i>Mycobacterium bovis</i> (ATCC 35743)	Not reviewed; Superseded by MRID 51199301
51199301				2 minutes				Yes
50964734	Disinfection, Fungicidal	Hard, non-porous surfaces	Towelette	2 minutes	5%	N/A	• <i>Candida albicans</i> , ATCC 10231	No*
50964735							• <i>Candida auris</i> , AR Bank#0381	Yes
50964736	Disinfection, Virucidal	Hard, non-porous surfaces	Towelette	2 minutes	5%	N/A	• Herpes simplex virus type 1 (ATCC VR-733, Strain F1) • Herpes simplex virus type 2 (ATCC VR-734, Strain FG) • Influenza A virus, Strain A/Hong Kong/8/68, ATCC VR-1679 • Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72 • Human orthopneumovirus	Yes
50964737								
50964738								
50964739								
50964740								

50964741							(Respiratory Syncytial Virus), Strain: Long, ATCC VR-26	
50964742							<ul style="list-style-type: none"> • SARS-associated Coronavirus, Strain: CDC 200300592, ZeptoMetrix/CDC 	
50964743							<ul style="list-style-type: none"> • Measles Virus, Strain: Edmonston, ATCC VR-24 	
50964744							<ul style="list-style-type: none"> • Parainfluenza virus type 3, ATCC VR-93, Strain C243 	
50964745							<ul style="list-style-type: none"> • Duck Hepatitis B virus Strain: Grimaud, Hepadna Virus Testing, Inc. 	
50964746							<ul style="list-style-type: none"> • Bovine Viral Diarrhea Virus, strain: NADL, American BioResearch Lab 	
50964747							<ul style="list-style-type: none"> • Human Immunodeficiency Virus Type 1 (HIV-1), Strain: IIIB, ZeptoMetrix 	
50964748							<ul style="list-style-type: none"> • Feline Calicivirus as a surrogate virus for Norovirus • Enterovirus 71, Strain: H Source: ATCC VR-1432 	

50964749							<ul style="list-style-type: none"> • Adenovirus type 2, ATCC VR-846, Strain Adenoid 6 • Human Rotavirus, ATCC VR-2018, Strain WA • Echovirus type 11, ATCC VR-41, Strain Gregory 	
50964750								
50964751								
50964749	Enveloped Viruses	Hard, non-porous surfaces	Towelette	2 minutes	5%	N/A	<ul style="list-style-type: none"> • Adenovirus type 2, ATCC VR-846, Strain Adenoid 6 • Feline Calicivirus as a surrogate virus for Norovirus • Enterovirus 71, Strain: H Source: ATCC VR-1432 	Yes
50964747	Large non-enveloped							
50964748	Small non-enveloped							

*Base fungicidal claim against T. interdigitale must first be met prior to additional organisms

VI LABEL COMMENTS

46781-RT/ Label date: 5/18/20

1. The proposed label claims that the product, CWN-07-W, a RTU towelette, is an effective bactericidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 2-minute contact time:

Staphylococcus aureus (ATCC 6538)
Pseudomonas aeruginosa (ATCC 15442)
Salmonella enterica (ATCC 10708)
Enterococcus faecium (ATCC 51559)
Klebsiella pneumoniae (ATCC 4352)
Acinetobacter baumannii (ATCC 19606)
Escherichia coli O157:H7 (ATCC 35150)
Legionella pneumophila (ATCC 33153)
Micrococcus luteus (ATCC 14408)
Burkholderia cepacia (ATCC 25416)
Streptococcus mutans (ATCC 2175)
Bordetella pertussis (ATCC 12743)
Moraxella catarrhalis (ATCC 25240)
Stenotrophomonas maltophilia (ATCC 25596)
Streptococcus pyogenes (ATCC 12344)
Penicillin-Resistant *Streptococcus pneumoniae* (PRSP) (ATCC 700677)
Vancomycin-Resistant *Enterococcus faecalis* (VRE) (ATCC 51575)
Methicillin-Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)
Carbapenem-Resistant *Klebsiella pneumoniae* (CRKP) (ATCC BAA-1705)
Multi Drug-Resistant *Acinetobacter baumannii* (ATCC BAA-1605)
Vancomycin-Intermediate *Staphylococcus aureus* (VISA), (ATCC 700699)
New Delhi metallo-beta-lactamase 1 (NDM-1-Positive) *Enterobacter cloacae* (CDC AR-0038)

These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, CWN-07-W, a RTU towelette, is an effective fungicidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 2-minute contact time:

Candida albicans, ATCC 10231

These claims are **not acceptable** as they are not supported by the submitted data. Fungicidal base claims must be satisfied with acceptable testing against *T. interdigitale* prior to adding additional fungal organisms.

3. The proposed label claims that the product, CWN-07-W, a RTU towelette, is an effective fungicidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 2-minute contact time:

Candida auris, CDC AR Bank#0381

These claims are **acceptable** as they are supported by the submitted data.

4. The proposed label claims that the product, CWN-07-W, a RTU towelette, is an effective virucidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 2-minute contact time:

Herpes simplex virus type 1 (ATCC VR-733, Strain F1)
Herpes simplex virus type 2 (ATCC VR-734, Strain FG)
Influenza A virus, Strain A/Hong Kong/8/68, ATCC VR-1679
Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72
Human orthopneumovirus (Respiratory Syncytial Virus), Strain: Long, ATCC VR-26
SARS-associated Coronavirus, Strain: CDC 200300592, ZeptoMetrix/CDC
Measles Virus, Strain: Edmonston, ATCC VR-24
Parainfluenza virus type 3, ATCC VR-93, Strain C243
Duck Hepatitis B virus Strain: Grimaud, Hepadna Virus Testing, Inc.
Bovine Viral Diarrhea Virus, strain: NADL, American BioResearch Lab
Human Immunodeficiency Virus Type 1 (HIV-1), Strain: IIIB, ZeptoMetrix
Feline Calicivirus as a surrogate virus for Norovirus
Enterovirus 71, Strain: H Source: ATCC VR-1432
Adenovirus type 2, ATCC VR-846, Strain Adenoid 6
Human Rotavirus, ATCC VR-2018, Strain WA
Echovirus type 11, ATCC VR-41, Strain Gregory

These claims are **acceptable** as they are supported by the submitted data.

5. The proposed label claims that the product, CWN-07-W, a RTU towelette, is an effective tuberculocidal disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 2-minute contact time:

Mycobacterium bovis (ATCC 35743)

These claims are **acceptable** as they are supported by the submitted data

6. The proposed label claims that the product, CWN-07-W, qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to EPA (dated: 7/6/2020):

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	One of the following: Adenovirus type 2, ATCC VR-846, Strain Adenoid 6 Feline Calicivirus as a surrogate virus for Norovirus Enterovirus 71, Strain: H Source: ATCC VR-1432
Large Non-enveloped	One of the following: Adenovirus type 2, ATCC VR-846, Strain Adenoid 6 Feline Calicivirus as a surrogate virus for Norovirus Enterovirus 71, Strain: H Source: ATCC VR-1432
Small Non-enveloped	Two of the following: Feline Calicivirus as a surrogate virus for Norovirus Enterovirus 71, Strain: H Source: ATCC VR-1432

These claims are **acceptable** as they are supported by the cited data.

Make the following changes to the proposed Emerging Viral Pathogens label language (and “Terms of Registration” letter, as applicable):

The proposed label language on page 4 should exactly match the following:

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

- Enveloped Viruses
- Large Non-enveloped
- Small Non-enveloped

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Adenovirus Type 2
Large Non-enveloped	Feline Calicivirus
Small Non-enveloped	Feline Calicivirus Enterovirus Type 71

Acceptable claim language:

(CWN-07-W) **[Product name]** has demonstrated effectiveness against viruses similar to **[name of emerging enveloped/small and large non-enveloped virus]** on hard, non-porous surfaces. Therefore, (CWN-07-W) **[product name]** can be used against **[name of emerging enveloped/small and large non-enveloped virus]** when used in accordance with the directions for use against (cited above) on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging enveloped/small and large non-enveloped virus]**. (CWN-07-W) **[Product name]** kills similar viruses and therefore can be used against **[name of emerging enveloped/small and large non-enveloped virus]** when used in accordance with the directions for use against (cited above) on hard non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

7. Make the following changes to the proposed label:

- a. Throughout the label, remove “Candidacidal” and “yeastocidal.” The agency does not have definitions for these terms.
- b. Qualify each instance of “eliminate”, “eliminates”, or “wipes out” with 99.9% or appropriate percentage kill as supported by data. The stand-alone eliminate claim may be misleading and imply complete kill.
- c. For all fungicidal claims, qualify to specifically identify *Candida auris*. These claims should remain qualified until the product has supporting data on *Trichophyton interdigitale*, which is the base organism needed to support fungicidal claims per agency guidelines (810.2000). Due to public health need, the agency has made exceptions to allow the *C. auris* claim. *Candida albicans* should be removed until the base fungi claim is supported.
- d. On page 5 of the label, remove “non-semi critical” as this is not a classification for medical devices. For semicritical devices, this product may only be used to pre-clean, not disinfect.
- e. On page 6 of the label, remove directions for use to disinfect ultrasound transducers or probes as these are semi-critical devices and fall under FDA jurisdiction.
- f. On page 9 of the label, revise “minimum” to “up to 99.999%”.
- g. On pages 9 and 16, remove “germ fighting” or “fight(s)” as this may be misleading regarding the activity of the product. An acceptable alternative is “kills germs”.
- h. On pages 11 and 19 of the proposed label, remove the term “common” from the claim “kills common household germs”.
- i. On pages 11, 12, 15, 16, 17 and 18 of the proposed label, remove the term “quick” from disinfection claims, as this claim must be qualified with a 30 second contact time.
- j. On page 13 of the propose label, remove “prevent[s] and/or” and add “on treated hard non-porous surfaces” to the claim “help[s] prevent[s] -and/or reduce[s] the spread of [99.9% of] [illness-causing] [clinically relevant] [bacteria] [pathogens] [organisms] - and/or- viruses* -and/or- germs on hard, non-porous surfaces”.
- k. On page 15 of the proposed label remove the following claims:
 - i. “Infection Prevention”
 - ii. “protect patients”These claims are misleading per the label review manual.

- l. On page 15 add “on treated surfaces” to the claim “reduce the risk of cross contamination”.
- m. On page 16 of the label, qualify “pseudomonacidal” with the specific organism tested, as the existing claim is too broad and may imply efficacy against the entire genus.
- n. On pages 16 and 18 of the proposed label remove the brackets from “on treated surfaces” as this is mandatory language.
- o. On pages 16 and 17 of the proposed label remove the claim “[Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus*. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza A virus* tested and listed on this label and is expected to inactivate all Influenza A virus* including Pandemic 2009 H1N1 (formerly called swine flu)]”, this guidance was superseded by the Emerging Viral pathogen guidance.
- p. On page 18 of the proposed label, remove the claim “To reduce cross-contamination from hard non-porous dental impressions for both dentist office personnel and dental laboratory personnel”. Claims may only be made for treated surfaces, not people.
- q. On pages 27-29, all semi-critical devices should be removed or clearly specified for pre-cleaning only. The product may only be used to disinfect non-critical devices. On page 29, remove brackets from “above the water line” as this specification is not optional for toilets. Any surfaces that may be hot or refrigerated, should be qualified with instructions to allow surfaces to come to room temperature prior to treatment (e.g. refrigerators, stoves, stovetops, etc.).